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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,080	02/20/2004	Todd Manegold	3071.TDM	6264

7590 05/02/2007
Cynthia L. Foulke
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Bridgewater, NJ 08807-0500

EXAMINER

MAEWALL, SNIGDHA

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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05/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/783,080

Applicant(s)

MANEGOLD ET AL.

Examiner

Snigdha Maewall

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. §1133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 09/27/05 and 09/30/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Summary

1. Receipt of IDS filed on 09/27/2005 and 09/30/2005 is acknowledged.
Claims 1-20 are pending in this application and claims 1-20 will be prosecuted on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
3. Claims 7-10 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-10 and 14 recite the limitation "at least about" with respect to the amounts of caffeine, percentages of caffeine and modified starch. The phrase "at least about" does not define the specific range limitations, as such rendering the claims indefinite.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1615

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-6 and 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Majeti (US patent No. 5,599,554).

Majeti discloses transdermally or transmucosally administrable composition in the form of mucoadhesive or bioadhesive films for the treatment and /or smoking withdrawal symptoms (abstract and column 2, lines 18-23 and column 3, lines 17-20). The composition comprises caffeine, which is slightly soluble in water and alcohol (column 3, lines 17-20). The various amounts of caffeine are used in the dosage form are listed on column 4, lines 10-23). Majeti further suggests that the amount of caffeine and frequency of administration may vary depending on the carrier and the personal needs of the user (column 4, lines 24-26). Majeti discloses that a variety of additional pharmaceutically acceptable ingredients may be added such as disintegration agents (column 6, lines 25-27).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1615

7. Claims 7-9 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US patent No. 5,599,554).

The teachings of Majeti have been discussed above. Majeti does not specifically disclose the claimed percentage or amount of caffeine in the composition. It is to be noted that with respect to the claimed percentages and amount of caffeine, it is the position of the examiner that optimization of such parameters would have been within the purview of a skilled artisan at the time the invention was made by performing manipulative experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

8. Claims 1-5, 10-13 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballard et al. (US Pg Pub. 2005/0013847 A1).

Ballard et al. discloses a delivery system comprising a homogenous, thermoreversible gel film comprising film formers, active substance, bulking agent and pH controlling agent along with the process of manufacture of such films (abstract and page 1 paragraph [0002]). Ballard et al. disclose variety of film forming agents which includes modified starches (see page 1 paragraph [0004 and page 2, paragraph [0021]). Various modified starches are listed on page 3, paragraph [0024] including the claimed hydroxylpropylated starches. The films as disclosed contain active substances such as oral care agent, a breath freshening agent, a pharmaceutical agent, a nutraceutical, vitamin, a flavorant or a food (see page 2 paragraph [0018] and claim 2). Ballard et al.

further disclose that the water content in the film ranges from 5-15% (page 3, paragraph [0028]). The process of manufacturing which involves mixing, coating, drying and molding or casting into films have been detailed on page 3 paragraph [0031] and [0044].

Although Ballard et al. do not specifically teach the claimed drug solubility, since they teach generic "pharmaceutical agent" and also "vitamins", which then includes lipophilic (vitamin A, E, D and K) compounds also, it would have been obvious to one of ordinary skill in the art to select these lipophilic compounds with low solubility from the teachings of Ballard et al. with a reasonable expectation of success.

9. Claims 6-9, 14-15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballard et al. (US Pg Pub. 2005/0013847 A1) in view of Majeti (US patent No. 5,599,554).

The teachings of Ballard et al. have been discussed above. Ballard et al. teaches that the films as disclosed contain active substances such as oral care agent, a breath freshening agent, a pharmaceutical agent, a nutraceutical, vitamin, a flavorant or a food (see page 2 paragraph [0018]). Ballard et al. does not specifically teach active ingredient caffeine.

Majeti (US patent No. 5,599,554) as discussed above under section 5 teaches active ingredient caffeine and its use in the treatment and/or smoking withdrawal symptoms in the form of trans-mucosally administrable film.

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate caffeine as active ingredient in forming a bio-adhesive film by Ballard et al. because of medicinal benefits of caffeine. A skilled artisan would thus have been motivated at the time the invention was made to formulate a dissolvable film comprising caffeine and modified starch with a reasonable expectation of success. Further, it is to be noted that with respect to the claimed percentages and amounts of caffeine in claims 7-9 and 14-15, it is the position of the examiner that optimization of such parameters would have been within the purview of a skilled artisan at the time the invention was made by performing manipulative experimentation.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the

Art Unit: 1615

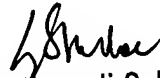
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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

Art Unit 1615


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Group 1600